REMARKS

Remarks

Applicants thank Examiner for the withdrawal of the rejections made in the previous Action. Examiner has made the following rejections in this action.

- Claims 80, 94 – 101 are rejected on the ground of nonstatutory obviousness-type double patenting.
- Claims 80 and 94 are rejected under 35 USC 112, second paragraph for lack of antecedent basis.
- Claims 80 and 94 – 101 (Action recites Claim 89 and 945 – 101 which Applicants assume to be in error) under 35 USC 112, first paragraph for allegedly containing new matter.
- Claims 80 and 101 are rejected under 35 USC 103(a) as being unpatentable over Dalum in view of both Kjerrulf and Tang.
- Claims 80, 94 – 97, 100 and 101 are rejected under 35 USC 103(a) as being unpatentable over Dalum taken with both Kjerrulf and Tang and in further view of Ferro, Sacca and Johnston.
- Claims 80, 98 and 101 are rejected under 35 USC 103(a) as being unpatentable over Dalum taken with Kjerrulf and Tang, in further view of Hohlfeld.

Double Patenting

Claims 80, 94 – 101 are rejected on the ground of nonstatutory obviousness-type double patenting as being "unpatentable over claims 1 – 4 and 7 – 16 of U.S. Patent No. 6,660,721." Pending Action, page 4. Applicants note that the correct number of the patent to which the Examiner refers to is 6,660,271) (the '271 patent). Applicants disagree that the pending claims are obvious variants of the recited claims of the '271 patent. However, Applicants herein attach a Terminal Disclaimer be filed in view of the '271 to overcome an obviousness type double patenting rejection. In response to this rejection, Applicants have prepared and submitted concurrently an executed Terminal Disclaimer. It is respectfully submitted that the filing of this document serves to obviate the grounds of rejection.

Examiner commented that "the instant application claims priority to US Patent No. 6,660,721 as being it's divisional, no restriction is on file for the '721 patent." The instant application claims priority to US Application No. 09/964,201, filed Sept. 26, 2001 (now US Patent No. 6,660,271) which is divisional of US Application No. 09/964,279 filed Feb. 19, 1998 (now US Patent No. 6,319,503) as listed in the instant applications Application Data Sheet. Applicants respectfully submit that the priority is properly claimed in the instant application.

Rejection Under 35 USC § 112, second paragraph

Claims 80 and 94 (and Claims 95 – 101 for being dependent upon rejected Claims 80 and 94) have been rejected as being indefinite for the recitation of the phrase "the antibody to be detected." Examiner states that there is insufficient antecedent basis for this limitation. Applicants have reviewed Claims 80 and 94 and have not found the phrase recited by Examiner. Rather, Applicants have found the phrase "an antibody to be detected" which has sufficient antecedent basis. In view of this, Applicants respectfully request that the rejection be withdrawn.

Rejection Under 35 USC § 112, first paragraph, New Matter

Examiner has rejected Claims 80 and 94 – 101 (Action recites Claim 89 and 945 – 101 which Applicants assume to be in error) for allegedly incorporating new matter and, therefore, failing to comply with the Written Description requirement. Specifically, Examiner states that the "specification failed to provide literal support for the recitation of 'one or more epitopes identical to the epitopes of the other non-contiguous epitope-containing segments.'" Pending Action, page 7.

Examiner is respectfully reminded that Applicants need not provide "literal support" for a claim limitation in order to satisfy the Written Description requirement. Rather, "While there is no *in haec verba* requirement, newly added claim limitations must be supported in the specification through express, implicit, or inherent disclosure. MPEP 2163(I)(B). Applicants respectfully submit that such *implicit* and *inherent* disclosure for the claim limitation added in the preceding Response is provided by the specification, as filed. Additionally, claims as originally filed are presumed to support the Written Description requirement because the claims are part of the specification.

The original claims as filed in the pending Application recited "...a fusion protein comprising a heat shock protein fused to two or more non-contiguous epitope-containing segments, each epitope containing segment comprising one or more identical or non-identical epitopes..." Applicant submits that if each of the non-contiguous segments contained "one or more identical epitopes" than it is inherent that one of the identical epitopes must be in one of the epitope-containing segments and the other identical epitope must be located in one of the other epitope-containing segments. Thus, it can be seen that the present language of the pending claims merely clarifies the Applicants' invention as originally filed and claimed and does not, as Examiner stated, add new matter to the specification. Support for the claims as originally filed may be found in the published application, for example, at paragraph [0023]. In view of the forgoing, Applicants respectfully request the withdrawal of the pending rejection.

Rejection Under 35 USC § 103

The Examiner has rejected Claims 80 and 101 under USC § 103(a) as being unpatentable over Dalum, *et al.*, in view of both Kjerrulf, *et al.*, and Tang, *et al.* More specifically, the Patent Office states:

> "It would have been obvious to one of skill in the art, at the time the invention was made, to modify the fusion protein of Dalum et al. by incorporating two or more copies of OVA epitopes, with a reasonable expectation of success. One of skill in the art would have been modified to do so because Kjerrulf et al. teach that fusion protein comprising more copies of the same epitope are more immunogenic. One of skill in the art would have been expected to have a reasonable expectation of success in making and using such a composition because the art teaches that such compositions can be successfully obtained and used. Dalum et al. taken with Kjerrulf et al do not teach a DNA vaccine. Tang et al. teach DNA vaccines as being able to product efficient immune responses. It would have been obvious to one of skill in the art, at the time the invention was made, to further modify the method of Dalum et al. and Kjerrulf et al. by using a DNA vaccine to elicit an immune response to their fusion protein with a reasonable expectation of success." Pending Action, page 9.

The Applicants respectfully traverse the rejection. A finding of obviousness requires 1) the teaching of each element of the claimed invention in the prior art, 2) there must be in the art motivation to combine the references and 3) the art must provide a reasonable expectation of

success.[1] MPEP 2143. The cited references, alone or in combination, do not teach or suggest synthesis of a DNA vaccine encoding a fusion of a heat shock protein such as ubiquitin with multiple epitopes would result in an immune reaction. Since none of the references exemplify synthesis of this DNA vaccine, none of the references could possibly teach that such a DNA vaccine would be effective in eliciting an immune response. As such, one of skill in the art would not be able to deduce from the teachings of the combination of Dalum, et al., Kjerrulf, et al., and Tang, et al, that a DNA vaccine of Applicant's Claims 80 and 101 would be able to elicit an immune response. The separate teachings of a heat shock fusion protein, multiple epitopes and using DNA constructs to produce antibodies does not amount to a teaching of the present invention nor give one skilled in the art the motivation or a reasonable expectation of success, and the combination of references cited does not cure this deficiency. *In fact, Tang, et al., teach against any reasonable expectation of success when they teach the use of their DNA discoveries and techniques for vaccination as merely "speculative"*[2]. Prior to Applicant's invention, one of skill in the art would not have been able to predict with cue any degree of certainty that a DNA vaccine encoding a fusion of a heat shock protein with multiple epitopes would result in an immune reaction. Based on the forging, Applicants respectfully request withdrawal of the pending rejection.

Rejection Under 35 USC § 103

The Examiner has rejected Claims 80, 94 – 97, 100 and 101 under USC § 103(a) as being unpatentable over Dalum, *et al.*, taken with both Kjerrulf, *et al.*, and Tang, *et al.*, in further view of each Ferro, *et al.,* Sacca and Johnston, *et al.* More specifically, the Patent Office states:

> "It would have been obvious to one of skill in the art, at the time the invention was made, to use the method of Dalum et al., Kjerrulf, et al., and Tang et al. to make

---

1 In regards to biotechnical/chemical cases the Federal Circuit, in a post KSR decision, determined in *Takeda Chemical Indus. v. Alphapharm Pty. Ltd.* that the TSM test in the field of chemistry and biotechnology satisfies the legal principles enunciated by the Supreme Court in KSR. The Court stated: "That test [TSM] for *prima facie* obviousness ... is consistent with the legal principles enunciated in KSR." *Takeda Chemical Indus. v. Alphapharm Pty., Ltd.*, No. 06-1329 (Fed. Cir. June 28, 2007, p 10). Thus, the TSM test is the proper standard to use in the pending application.

2 "The second, more speculative [use], is the genetic vaccination of animals against pathogenic infections..." Tang, et al., page 154, paragraph bridging first and second column.

> a DNA vaccine encoding a fusion ubiquitin-GnRh or ubiquitin-hGH, with a reasonable expectation of success." Pending Action, page 10

Applicants respectively traverse the rejection. Applicant's arguments in regards to Dalum, *et al.*, taken with both Kjerrulf, *et al.*, and Tang, *et al.*, are presented above and are applied here. Ferro, Sacca and Johnston, in combination with Dalum, *et al.*, taken with both Kjerrulf, *et al.*, and Tang, *et al.*, do not cure the defects in the cited art, as noted above. As such, one of skill in the art would not be able to deduce from the teachings of the combination of Dalum, et al., Kjerrulf, et al., and Tang, et al, in view of each Ferro, *et al.,* Sacca and Johnston, *et al.*, that a DNA vaccine of Applicant's Claims 80, 94, 98, 100 and 101 would be able to elicit an the immune responses as claimed. The separate teachings of a heat shock fusion protein, multiple epitopes, using DNA constructs to produce antibodies immunoneutralizing GnRh or hGH and using non-ubiquitin carriers does not amount to a teaching of the present invention nor give one skilled in the art the motivation or a reasonable expectation of success, and the combination of references cited does not cure this deficiency. *In fact, Tang, et al., teach against any reasonable expectation of success when they teach the use of their DNA discoveries and techniques as a vaccine is merely "speculative"*[3]. Prior to Applicant's invention, one of skill in the art would not have been able to predict with cue any degree of certainty that a DNA vaccine encoding a fusion of a heat shock protein with multiple epitopes would result in the immune reaction as claimed. Based on the forging, Applicants respectfully request withdrawal of the pending rejection.

Rejection Under 35 USC § 103

The Examiner has rejected Claims 80, 98 and 101 under USC § 103(a) as being unpatentable over Dalum, *et al.*, taken with both Kjerrulf, *et al.*, and Tang, *et al.*, in further view of Hohlfeld, *et al.* More specifically, the Patent Office states:

> "It would have been obvious to one of skill in the art, at the time the present invention was made, to use the method of Dalum et al., Kjerrulf, et al., and Tang et al. to make a DNA vaccine encoding a fusion ubiquitin-TNF-α vaccine with a reasonable expectation of success." Pending Action, page 12.

---

[3] Ibid..

Applicants respectively traverse the rejection. Applicant's arguments in regards to Dalum, *et al.*, taken with both Kjerrulf, *et al.*, and Tang, *et al.*, are presented above and are applied here. Hohlfeld, in combination with Dalum, *et al.*, taken with both Kjerrulf, *et al.*, and Tang, *et al.*, do not cure the defects in the cited art, as noted above. As such, one of skill in the art would not be able to deduce from the teachings of the combination of Dalum, et al., Kjerrulf, et al., and Tang, et al, in view of Hohlfeld, *et al.*, that a DNA vaccine of Applicant's Claims 80, 98, and 101 would be able to elicit an the immune response as claimed. The separate teachings of a heat shock fusion protein, multiple epitopes, using DNA constructs to produce antibodies immunoneutralizing TNF-α does not amount to a teaching of the present invention nor give one skilled in the art the motivation or a reasonable expectation of success, and the combination of references cited does not cure this deficiency. *In fact, Tang, et al., teach against any reasonable expectation of success when they teach the use of their DNA discoveries and techniques as a vaccine is merely "speculative"*[4]. Prior to Applicant's invention, one of skill in the art would not have been able to predict with cue any degree of certainty that a DNA vaccine encoding a fusion of a heat shock protein with multiple epitopes would result in the immune reaction as claimed. Based on the forging, Applicants respectfully request withdrawal of the pending rejection.

---

[4] Ibid.

Summary

In light of the above arguments, consideration of the subject patent application is respectfully requested. Applicants submit that all pending rejections have been overcome. Applicants request that the rejections be withdrawn and the application passed to allowance. Any deficiency or overpayment should be charged or credited to Deposit Account No. 500282.

Respectfully submitted,

Kevin M. Farrell
Attorney for Applicants
Registration No. 35,505
(603) 433-6300

Portsmouth, NH
Date: 12/6/07

P0175174.DOC